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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,210	03/17/2005	Stephen R. Smith	3323	9149

21834 7590 02/01/2010

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ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
02/01/2010	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN R. SMITH, STEWART J. RITCHIE,
and GUOPENG ZHANG

Appeal 2009-013140
Application 10/528,210
Technology Center 1600

Decided: February 1, 2010

Before TONI R. SCHEINER, RICHARD M. LEBOVITZ, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an antimicrobial composition. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

"Every year NE [necrotic enteritis], CPE [*Clostridium perfringens* enteritis] and diarrheal diseases impose significant financial losses to the bird and pig farming industries" (Spec. 1 ¶ 0002). According to the Specification, the "continued development of resistance to and against feed grade antibiotics, however, has caused a setback in the prevention and control of the above-mentioned diseases" (Spec. 2 ¶ 0006). The Specification teaches that "[o]ne of the most significant problems associated with the reduction and elimination of antibiotics for use in poultry and swine will be the increase in incidences of NE, along with a potential increase in incidences of CPE and diarrheal disease" (Spec. 3 ¶ 0006).

The Specification teaches "an improved antimicrobial composition and method for administering the same to assist in controlling enteric pathogenic infection in livestock and more particularly in avian and swine populations" (Spec. 3 ¶ 0007).

The Claims

Claims 49-69 are on appeal. Claims 49 and 68 are representative and read as follows:

> 49. An orally administrable antimicrobial composition for suppressing the growth of enteric pathogens in the gut of livestock, the antimicrobial composition comprising:
>
> (a) a cell wall lysing substance or its salt;
>
> (b) at least one of dried egg powder and albumen; and
>
> (c) a sequestering agent.

68. An orally administrable antimicrobial composition for treating gastrointestinal infections in livestock, the antimicrobial composition comprising:

(a) a cell wall lysing substance or its salt;
(b) at least one of dried egg powder and albumen;
(c) a sequestering agent; and
(d) a lantibiotic.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Anderson (Unilever)	EP 0 466 244 A1	Jan. 15, 1992
Mican (Medipharm)	EP 0 955 061 A1	Nov. 10, 1999
Iwasaki et al. (Nippon) (translation)	JP 62-145025 A	Jun. 29, 1987

H. R. Ibrahim, *Ovotransferrin, in* NATURAL FOOD ANTIMICROBIAL SYSTEMS, 211-226 (A.S. Naidu ed., 2000).

The issue

The Examiner rejected claims 49-60 under 35 U.S.C. § 103(a) as obvious over Unilever, Medipharm, Ibrahim, and Nippon (Ans. 3-7).

The Examiner finds that Unilever discloses "a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant" (*id.* at 4). The Examiner finds that Unilever teaches "suppression of microorganisms in production, packaging and storage of food products, animal feeds" (*id.*). The Examiner finds that Medipharm "discloses an oral product for the prevention and therapy of porcine gastroenteric infections . . . . The oral compositions raw material is liquid eggs, which are freeze-dried resulting in

a powder form product" (*id.* at 5). The Examiner finds that Ibrahim "discloses that an avian egg is one of many natural antimicrobial systems available" (Ans. 5). The Examiner finds that Nippon discloses "albumen as an active component for the suppression of viruses such as rotavirus" (*id.* at 6). The Examiner finds that "one of skill in the art would expect success in administering a composition comprising components which are known in the art for their antibacterial properties and effectiveness against enteric pathogens" (*id.* at 10).

Appellants argue that "Unilever focuses exclusively on the ex vivo problem of safe food preparation, preservation and storage. In contrast, Appellant's composition focuses exclusively on the in vivo problem of animal health. Thus, Unilever's composition is not in the same field of endeavor as Appellant's composition" (App. Br. 7). Appellants argue that "there existed no teaching nor motivation nor suggestion in any of the cited art to combine an ex vivo agent with an in vivo agent" (*id.* at 8). Appellants argue that "[t]here is no teaching in Unilever that the lysozyme composition would be able to withstand the gastric digestion within the gut of livestock" (*id.* at 9).

Appellants also argue that the ordinary artisan would "have been faced with a large number of potential agents to add to combat in vivo bacteria, so the selection of egg would have required an inventive inspiration" (App. Br. 10). Appellants argue that the claimed "composition provides synergistic effects that would not be expected from the known qualities of its components" (App. Br. 13).

In view of these conflicting positions, we frame the obviousness issue before us as follows:

Have Appellants demonstrated that the Examiner erred in finding it obvious to modify the antibacterial composition of Unilever to incorporate the dried egg powder of Medipharm or albumen of Nippon?

Findings of Fact (FF)

1. The Specification teaches that "the sequestering agent may be an organic acid and/or a metal-chelator and may be selected from disodium ethylenediaminetetraacetate (EDTA), citric acid or chitosan" (Spec. 4-5 ¶ 0015).

2. Unilever teaches that a "mixture of (1) a cell wall lysing substance such as lysozyme, (2) an antibacterial such as the bacteriocin nisin, and (3) citric acid or a salt thereof or another food-grade adjuvant, effectively prevents growth of *Listeria monocytogenes* bacteria. It is also effective against other micro-organisms e.g. *Bacillus* species" (Unilever abstract).

3. Unilever teaches that the "main application of this invention is in connection with the production, packaging and storage of food products . . . but the invention can also be applied for non-food uses, examples of which comprise animal feedstuffs, cosmetic products, and pharmaceutical products" (Unilever 3, ll. 47-49).

4. Medipharm teaches that a "raw material, in this case liquid eggs, obtained from the immunized donors is homogenized and preserved by spray, or fluid or freeze-drying" (Medipharm 3, ll. 32-34).

5. Medipharm teaches that the "product is intended exclusively for oral administration to piglets, weaners and older pigs at various stages of the postnatal development and therefore a paste formula and a powder formula have been devised" (Medipharm 3, ll. 51-53).

6. Nippon teaches that albumen has "an anti-viral action" (Nippon translation 3).

7. Nippon teaches that the "albumen used may be raw albumen and frozen albumen and the like and there are no particular restrictions as long as it contains raw albumen" (Nippon translation 3).

8. Nippon teaches that there "are no particular restrictions on the administration of the anti-viral agent . . . and it may be administered to humans, cows, horses, goats, pigs and other livestock" (Nippon translation 3).

9. Nippon teaches that "when administered in the form of albumen, it should be at least 0.01 g and preferably approximately 0.03 to 3 g. Moreover, it is usually administered orally" (Nippon translation 3-4).

10. Nippon teaches that the formulation "may be administered as is or it may be administered by adding it to water, milk, processed milk and other food or drink" (Nippon translation 4).

11. Nippon teaches that "another drug may be added to the anti-viral agent for homiothermal adults in the present invention" (Nippon translation 4).

Principles of Law

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art;

(2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

"[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," *KSR* directs that "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417.

"[A] preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). A preamble is not limiting, however, "'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" *Id.* (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).

Analysis

We begin with claim interpretation, and in particular, with determining whether the preamble of claim 49 is limiting. The preamble of Claim 49 states "[a]n orally administrable antimicrobial composition for suppressing the growth of enteric pathogens in the gut of livestock" (Claim

49). In this case, the composition of claim 49, requiring three structural elements, represents a situation where the claim body defines a structurally complete invention. The preamble is not necessary to give life or meaning to the claimed composition and functions solely to provide an intended use for the composition.

Unilever teaches a composition comprising a cell wall lysing substance, lysozyme, as well as a sequestering agent, citric acid (FF 2). Unilever teaches that this composition may be applied to animal feedstuffs (FF 3).

Medipharm teaches a freeze dried egg product, produced from eggs layed by immunized hens, to be fed to pigs for protection from disease (FF 4-5).

Nippon teaches that raw egg albumen has anti-viral properties and can be administered to animals (FF 6-9). Nippon teaches that the albumen may be administered directly or in combination with food or drink (FF 10). Nippon expressly recognizes that the albumen as an anti-viral agent may be combined with other drugs, noting that "another drug may be added to the anti-viral agent for homiothermal adults in the present invention" (Nippon translation 4; FF 11).

The ordinary artisan would have reasonably combined the antibacterial composition of Unilever with the raw egg albumen of Nippon or the freeze dried egg product of Medipharm since Unilever teaches that the antibacterial composition may be used to increase the safety of products being fed to animals (FF 2-3) and the egg products of Nippon and Medipharm were designed to be fed to animals as anti-viral agents (FF 4-

11). Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417.

Appellants argue that "Unilever focuses exclusively on the ex vivo problem of safe food preparation, preservation and storage. In contrast, Appellant's composition focuses exclusively on the in vivo problem of animal health. Thus, Unilever's composition is not in the same field of endeavor as Appellant's composition" (App. Br. 7). Appellants argue that "there existed no teaching nor motivation nor suggestion in any of the cited art to combine an ex vivo agent with an in vivo agent" (*id.* at 8).

We are not persuaded because this argument imposes a requirement that Appellants' intended use controls the analogous art question, a requirement which is not found in the caselaw. Rather, in *ICON*, the Federal Circuit explained that

> "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d 656, 659 (Fed.Cir.1992). In other words, "familiar items may have obvious uses beyond their primary purposes." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1742, . . . (2007).

In re ICON Health and Fitness, Inc., 496 F.3d 1374, 1379-1380 (Fed. Cir. 2007). Here, Nippon teaches that its product may be included in food (FF 10). Unilever is reasonably interpreted as pertinent since the Unilever composition is taught as useful in packaging and improving the safety of both "animal feedstuffs . . . and pharmaceutical products" (Unilever 3, ll. 47-49; FF 3). The ordinary artisan, interested in administering products of

Medipharm or Nippon to treat or prevent viral infection in animals, would reasonably have included the composition of Unilever for "suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products" (Ans. 6).

We are not persuaded by Appellants' argument that "[t]here is no teaching in Unilever that the lysozyme composition would be able to withstand the gastric digestion within the gut of livestock" (App. Br. 9). This argument is also drawn to Appellants' intended use for their composition. However, Appellants do not dispute that Unilever will protect the food and pharmaceutical products of Medipharm or Nippon prior to administration to an animal. This represents a sufficient reason to combine these references and render the claimed composition obvious.

We are not persuaded by Appellants' argument that the ordinary artisan would "have been faced with a large number of potential agents to add to combat in vivo bacteria, so the selection of egg would have required an inventive inspiration" (App. Br. 10). Medipharm and Nippon specifically teach immunized egg products and albumen respectively and the ordinary artisan interested in ensuring these products are not subject to bacterial contamination would have reasonably incorporated the composition of Unilever (*see* FF 2-11). *See In re Corkill*, 771 F.2d 1496, 1500 (Fed. Cir. 1985) (affirming obviousness rejection of claims in light of prior art teaching that "hydrated zeolites will work" in detergent formulations, even though "the inventors selected the zeolites of the claims from among 'thousands' of compounds").

Appellants argue that the claimed "composition provides synergistic effects that would not be expected from the known qualities of its components" (App. Br. 13). We are not persuaded since Appellants also specifically state that "Appellant has not submitted evidence regarding secondary considerations during prosecution of this case" (App. Br. 14). Therefore, Appellants' argument regarding unexpected results is not persuasive in the absence of evidence supporting such results. *See In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) ("It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements ... [do] not suffice.") *Also see In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.").

Conclusion of Law

Appellants have not demonstrated that the Examiner erred in finding it obvious to modify the antibacterial composition of Unilever to incorporate the dried egg powder of Medipharm or albumen of Nippon.

SUMMARY

In summary, we affirm the rejection of claim 49 under 35 U.S.C. § 103(a) over Unilever, Medipharm, Ibrahim, and Nippon. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 50-69 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

cdc

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